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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/596,194	06/16/00	KIRST	S 10147-25 (MB

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EXAMINER	
TAYLOR, T	
ART UNIT	**PAPER NUMBER**
1655	7

DATE MAILED: 07/31/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/596,194	Applicant(s) KIRST ET AL.	
	Examiner Janell Taylor Cleveland	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1023* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-23* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7 and 16-18, drawn to nucleic acids, classified in class 435, subclass 6.

II. Claims 8-10, 12, and 15, drawn to polypeptides, classified in class 530, subclass 350.

III. Claims 11 and 23, drawn to antibodies, classified in class 424, subclass 130.1.

IV. Claims 13 and 14, drawn to a method for detecting a polypeptide, classified in class 435, subclass 4.

V. Claims 19-20, drawn to a method for identifyng a compound which binds a polypeptide, classified in class 514, subclass 1.

VI. Claim 21, drawn to a method for modulating the activity of a polypeptide, classified in class 514, subclass 885.

VII. Claim 22, drawn to a method for identifying a compound which modulates the activity of a polypeptide, classified in class 514, subclass 885.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to a nucleic acid and a protein, which

have different functions, i.e., the nucleic acid codes for protein and the protein is used for various purposes in the cell, in the instant case as modulating agents. The nucleic acid is capable of functioning to code for a peptide without the peptide being present, and can be used by the practitioner to create probes, primers, and for diagnostic purposes without the presence of the peptide. Furthermore, the peptide is capable of functioning without the nucleic acid being present in the cell.

2. Inventions I, II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to nucleic acids, proteins and antibodies. The antibodies have different functions in the cell than either the protein or the nucleic acid, and are used for immunological purposes.

3. Inventions I, II, III and IV-VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the first three groups are drawn to different products (proteins, nucleic acids, and antibodies), and groups IV-VII are drawn to methods of using these products. Not only could the methods be practiced with a different product, but the products may be used with different methods.

4. Inventions IV, V, VI, and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions comprise different methods which contain different method steps. One method is drawn to detecting a polypeptide, while the other is drawn to a method for identifying a compound which binds the polypeptide. Another is drawn to modulating the activity of a polypeptide, while the last is drawn to identifying a compound which modulates this activity. These four methods contain different functions and have different effects, and involve different products.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. Because these inventions are distinct for the reasons given above and the search required for Group III is not required for Group IV, that required for Group IV is not required for Group V, that for Group V is not required for Group VI, and that for Group VI is not required for Group VII, restriction for examination purposes as indicated is proper.

7. These claims are generic to a plurality of disclosed patentably distinct restriction groups comprising different SEQ ID NOs. Applicant is required under 35 U.S.C. 121 to elect no more than 10 disclosed nucleic acids representing 10 different SEQ ID Nos.

This restriction requirement is based upon the notice in the Official Gazette in October 1996 which states, "Applications claiming more than ten (10) individual

independent and distinct nucleotide sequences in alternative form, such as set forth in example 1, will be subject to a restriction requirement. Only the ten (10) nucleotide sequences selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom will be examined."

Should applicant traverse on the ground that some or all of the different nucleic acids are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the nucleic acids to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Although the MPEP deems that up to ten nucleotide sequences may be searched without restriction, it has recently been decided by the Director of Biotechnology at the USPTO that searching more than one sequence per application will place an undue burden upon the Examiner and the Office. For this reason, restriction to ONE SEQUENCE is being applied to all applications at this time. Please note that for claims in which a nucleic acid sequence is given along with the corresponding polypeptide sequence, Applicant may choose both SEQ ID NOS as long as they correspond to the same nucleic acid/polypeptide. (In other words, if SEQ ID NO: 1 is drawn to a nucleic acid and SEQ ID NO: 2 is drawn to the corresponding polypeptide, Applicant may elect both SEQ ID NO: 1 and SEQ ID NO: 2 as long as they are both presented in the same claim.)

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janell Taylor Cleveland whose telephone number is 703-305-0273. The examiner can normally be reached on M-F 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-8724 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Janell Taylor Cleveland
Examiner
Art Unit 1655

Carla Myers
CARLA J. MYERS
PRIMARY EXAMINER

July 24, 2001